TCT-585

Drug Eluting Stent With Bioresorbable Polymer For Chronic Total Occlusion: 1 Year Outcomes From e-NOBORI Registry

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BACKGROUND Chronic total occlusion (CTO) recanalization is still a very challenging topic in the field of coronary intervention. Data on the performance of drug eluting stent (DES) with bioresorbable polymer in CTO are limited. The aim of our study is to assess 1-year clinical outcomes in CTO lesion management in a large worldwide registry.

METHODS In the large, prospective, single-arm, multi-center eNOBORI registry, 12139 patients were treated with Nobori DES. Among them 437 (3.6%) had at least one CTO lesion treated. An independent clinical events committee adjudicated all endpoint related adverse events. The primary endpoint was Target Lesion Failure (TLF) at 1 year.

RESULTS CTO patients were on average 60.7 years old and 82.4% are male, with a history of myocardial infarction, PTCA and cardiac surgery of 45.7%, 34.1% and 6.7%, respectively. 77.6% patients were hypertensive and 29.5% had diabetes. 68.7% patients were presented with stable angina while 13.3% had acute coronary syndrome. Lesions were located in the LAD (38.5%), RCA (37.6%), and LCX (22.6%). Multiple vessels were treated in 35.0% of patients (2.2±1.4 lesions treated per patient) with an average of 1.5±0.8 stents per lesion. Among all 751 treated lesions, 614 (81.8%) were complex B2/C type lesions, with 17.2% Ostial lesion, 49.1% moderate or severe calcified lesion, 62.6% CTO lesion, 2.8% had thrombus present and 7.3% were bifurcation. Pre- and post-dilatation were performed in 85.5% and 36.4% of lesions, respectively. Antegrade approach was chosen in the majority of procedures (88.2%), and a high frequency of single wire technique (79.0%) was used compared to parallel wire (13.4%) and seesaw wire (1.5%) techniques. Several other techniques were used for CTO treatment including CTO dedicated wires (38.4%), OTW balloon (8.5%), microcatheter (26.8%), rotational atherectomy (2.0%), cutting balloon (2.9%) and balloon dilatation only (4.7%). IVUS guidance was performed in 7.4% of patients. The average contrast volume and fluoro time were 269±124mL and 37.2±37.9 minutes, respectively. Procedural success rate was 98.2%. At 1 year follow up, 16 (3.7%) out of 437 patients had TLF. Three cardiac deaths (0.7%) and 7 target lesion revascularizations (1.6%) were reported at one year follow-up - together with 7 (1.6%) myocardial infarctions. A total of 80.8% of the patients were angina free at 1 year. Only 1 stent thrombosis (definite plus probable) was reported up to 1 year.

CONCLUSIONS Treatment of CTO with Nobori DES showed encouraging outcomes, although we cannot completely exclude the possibility that there might be underreporting of events, particularly periprocedural MIs might exist. One-year clinical outcomes suggest that this stent is a valuable treatment option for patients with CTO who are considered candidates for coronary interventions.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Bioabsorbable polymer, Chronic total occlusion, Drug-eluting stent

TCT-586

Comparison of second-generation with first-generation drug eluting stent for coronary chronic total occlusion intervention

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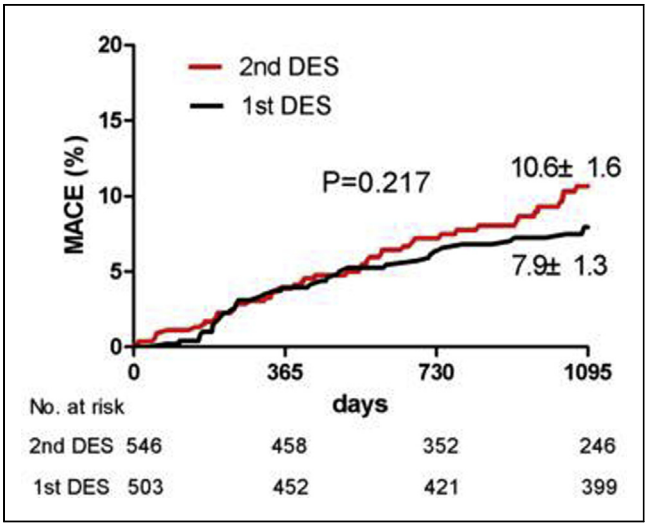
BACKGROUND Although second generation drug-eluting stents (DES) have improved angiographic and clinical outcomes over first-generation DESs, clinical efficacy and safety of second-generation DES for the percutaneous coronary intervention of chronic total occlusion (CTO) were not well defined.

METHODS We evaluated the 3-years clinical outcomes of 546 patients treated with second generation DES (everolimus- or zotarolimus-eluting stent) and 503 with first generation DES (sirolimus- or paclitaxel- eluting stent) for CTO in Asan Medical Center from 2004 to 2013. The primary endpoint was the incidence of major adverse cardiac events (MACE) at 3 years, defined as a composite of death, Q-wave myocardial infarction (MI), or target-vessel revascularization (TVR).

RESULTS The 3-year overall mortality of the second and first generation DES groups were not significantly different. (6.4±1.2% vs. 4.1±0.9%, P=0.12). After multivariable adjustment, there was no significant difference between patients who received second generation and first generation DES for the risk of MACE. (Hazard ratio [HR] 1.35, 95% confidence interval [CI] 0.85-2.12, P =0.20). The risk of death (HR 1.61, 95% CI 0.86-2.99, P =0.14), Q-wave MI (HR 1.41, 95% CI 0.40-4.95, P =0.59) and TVR (HR 0.86, 95% CI 0.41-1.76, p=0.67) were similar between the two groups. The incidence of definite/probable stent thrombosis was comparable (0.7% vs.1.0%, p=0.65) throughout the follow-up period.

Outcomes	Hazard ratio	95% confidence interval	*P* value
MACE	1.35	0.85-2.12	0.20
Death	1.61	0.86-2.99	0.14
Cardiac death	1.72	0.75-3.95	0.20
Myocardial infarction	1.41	0.40-4.95	0.59
Death and myocardial infarction	1.50	0.86-2.73	0.16
Target vessel revascularization	0.86	0.41-1.76	0.67
Any repeat revascularization	1.11	0.64-1.93	0.72

MACE = major adverse cardiovascular event.



CONCLUSIONS The 3-year clinical outcomes after CTO intervention using second generation DESs were not significantly different from those using first generation DESs.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Chronic total occlusion, Clinical outcomes, Drug-eluting stent

TCT-587

Bioabsorbable polymer-coated thin strut everolimus-eluting synergy stent for coronary revascularization in daily clinical practice: One-year results of the SWEET registry

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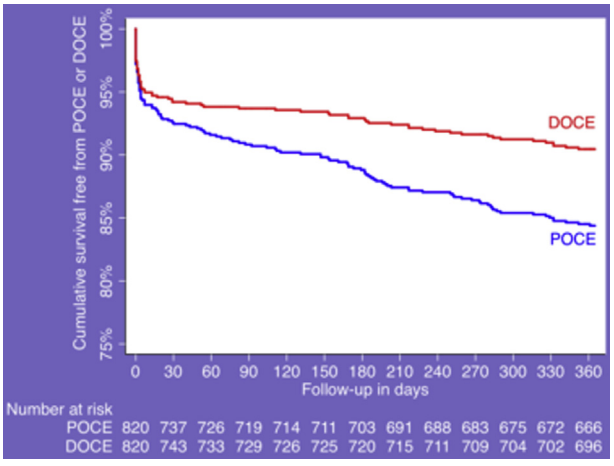
BACKGROUND Bioabsorbable polymer drug-eluting stents (DES) represent an indisputable improvement over first-generation DES

with promising results on long-term adverse events. We sought to determine the 1-year clinical follow-up in patients treated with the bioabsorbable polymer-coated everolimus-eluting SYNERGY stent in daily clinical routine.

METHODS All consecutive patients treated with the SYNERGY stent at University and Hospital Fribourg, La Tour Hospital Geneva and the University Hospital of Bern between December 2012 and June 2014 were prospectively included in the SWEET registry (SWiss Evaluation of bioabsorbable polymer-coated Everolimus-eluting coronary sTent). Clinical follow-up was performed at 1 year. The primary endpoint was the Academic Research Consortium (ARC) defined device-oriented composite of cardiac death (CD), myocardial infarction of the target vessel (TV-MI) and clinically indicated target lesion revascularization (CI-TLR) at 1 year.

RESULTS One thousand patients were included in the SWEET registry. Intermediate analysis was performed in the first 820 patients (1289 lesions) in whom 1-year follow-up was available. Mean age was 68±11 years and 73% (n=569) of patients were men. Diabetes mellitus was present in 22% (n=178) and a history of previous myocardial infarction in 18% (n=147) of patients. Acute Coronary Syndrome was the indication for stent implantation in 55% (n=451) of cases of which 22% (n=184) presented with STEMI. Median (25th-75thpercentile) SYNTAX score was 13 (7-21). Left main treatment was performed in 4% (n=30) and saphenous vein graft interventions in 3% (n=22) of patients. The primary endpoint occurred in 9.3% (n=76) of patients at 1 year (Figure 1). CD was 4.9% (n=40) and TV-MI occurred in 2.7% (n=22) of patients. CI-TLR was performed in 4.0% (n=33) of patients. The ARC-defined patient-oriented composite end point (all-cause mortality, any myocardial infarction, any revascularization) occurred in 15.2% (n=125) of patients at 1 year. ARC-defined definitive stent thrombosis occurred in 14 patients (1.7%) within the first year after stent implantation (early: 1.6% [n=13], late 0.1% [n=1]).



CONCLUSIONS The bioabsorbable polymer-coated thin strut everolimus-eluting SYNERGY stent yields a favorable safety and efficacy in daily clinical practice.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS All-Comer, Bioabsorbable polymer, Everolimus-eluting stents

TCT-588

Primary results of 2 years clinical investigation from en-ABL e-registry using novel abluminal coated sirolimus eluting stent with bio-degradable polymer matrix

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BACKGROUND Newer generation of drug eluting stents (DES) has attempted to improve safety using abluminal sirolimus drug delivery with biodegradable polymers matrix. Abluminus™ is sirolimus eluting stent with biodegradable polymer matrix coated on abluminal stent and parts balloon surface. The aim of en-ABL e-registry is to capture long term clinical data of the Abluminus by evaluation of safety and efficacy in large population in routine clinical practice.

METHODS The study is designed for all-comers by the prospective method in 3000 patients in India. The data was divided in 3 sub-set of patient; diabetic (n=300), MVD (n=200) and long lesion (n=200) subsets. Primary endpoint was major adverse cardiac events (MACE); defined as composite of cardiac death, myocardial infarction (MI), cardiac / non-cardiac death, target lesion revascularization (TLR) and target vessel revascularization (TVR) at 12 months. Major secondary endpoints were stent thrombosis (definite and probable according to ARC conditions) as acute, sub-acute and late thrombosis.

RESULTS We evaluated 1026 prospective patients 1342 devices and corresponding 1229 lesions. Mean age of population was 56.21 ± 10.63%, 81.77% were male, 36.65% patients were diabetic, small vessel < 2.5 mm were 49.87% and long lesion > 28 mm were 50.12%. Individual time domain % MACE are reported in table 1. One acute and one sub-acute stent thrombus events was reported.

Table 1. Individual adverse events (%) at different time points

Follow-up	1 month	3 months	9 months	12 months	24 months
Patients - follow-up	1020	963	798	692	157
Angiographic follow-up	-	-	99	-	-
MACE	0.10	0.19	1.35	0.1	0.1
Death	0	0	0	0	0
Cardiac death	0	0	0	0	0
MI	0	0	0	0	0
TVR/TLR	0.1	0.19	1.35	0.1	0.1

CONCLUSIONS Interim analysis has revealed a MACE rate 1.64% at 9 month follow-up and 2 events of stent which remains unchanged at 2 year follow-up. The data suggests safety and efficacy of DES in routine clinical practice. Further data will be presented during conference.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Abluminal Coating, Drug-eluting stent, sirolimus, Thrombolysis

TCT-589

The influence of the diabetic status on the clinical outcomes after percutaneous coronary intervention in the era of drug eluting stent: 5-year follow-up data from the Asan multi-vessel registry

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BACKGROUND The influence of diabetes mellitus (DM) on the clinical outcomes after PCI for the multi-vessel coronary artery disease (CAD) using drug eluting stent (DES) were not well defined to date.

METHODS We evaluated the clinical outcomes after PCI using DES for multi-vessel CAD in patients with or without DM. From January 2003 to December 2013, a total of 5057 patients underwent PCI for the multi-vessel CAD with (n=1738) or without (n=3319) DM were included. The primary outcome was the incidence of major adverse